IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michelle M. Hanna

Appl. No.: To be assigned (National Stage of

PCT/US2004/013031

Int'l Appl. Filing Date: April 29, 2004

For: Molecular Detection Systems Utilizing

Reiterative Oligonucleotide Synthesis

Confirmation No.: To be assigned

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 2072.0010009/MAC/SJE

Information Disclosure Statement

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of the cited documents were submitted to the Office in Information Disclosure Statements that comply with 37 C.F.R. § 1.98(a)-(c) in Application No. 10/425,037, filed April 29, 2004, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

JC05 Rec'd PCT/PTO 03 OCT 2005 10/551775

- 2 -

Michelle M. Hanna Appl. No. 10/488,971

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. No statement or fee is required. 37 C.F.R. § 1.97(b).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Simon J. Elliott

Agent for Applicant

Registration No. 54,083

Date: Octobe 3, 2005 1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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INFO			LOSURE STAT	EMENT	FIRST NAMED IN Michelle M. Hanna INT'L APPL. FILIN April 29, 2004	а		10/5 ART UNIT To be assigned	51775
				U.S. PA	TENT DOCUME	NTS			
EXAMINER INITIAL			UMENT IBER	DATE	NAME		CLASS	SUB-CLASS	FILING DATE
	AA1	3,99	6,345	12/07/1976	Ullman et al.				06/30/1975
	AB1	4,35	51,760	09/28/1982	Khanna et al.				09/07/1979
	AC1	4,58	32,788	04/15/1986	Erlich				01/07/1983
	AD1	4,68	33,194	07/28/1987	Saiki et al.				03/28/1985
	AE1	4,73	9,044	04/19/1988	Stabinsky				06/13/1985
	AF1	4,75	57,141	07/12/1988	Fung et al.				08/26/1985
	AG1	4,78	6,600	11/22/1988	Kramer et al.				05/25/1984
	AH1	5,13	30,238	07/14/1992	Malek et al.				08/23/1989
	Al1	5,16	9,766	12/08/1992	Schuster et al.				06/14/1991
	AJ1	5,50	8,178	04/16/1996	Rose et al.	4 (), (02/09/1994
	AK1	5,59	5,891	01/21/1997	Rose et al.				07/19/1990
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	AS	<u>1</u>	Chamberlin, M Academic Pre	M.J., "Bacterial ess, New York,	DNA-Dependent R N.Y. pp. 61, 84-86	NA Polymer (1982)	ases," in	The Enzymes, Bo	yer, P.D., ed.,
	АТ	1	Costas, C., et photocrosslin	al., "RNA-prot king ATP analo	ein crosslinking to A g," <i>Nucleic Acids F</i>	AMP residue Res. 28:1849	-1858, O	xford University P	ress (May 2000)
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

FIRST NAMED INVENTOR

Michelle M. Hanna
INT'L APPL. FILING DATE April 29, 200

APPLICATION NO.

To be assigned (National Phase of

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FILING DATE:	ARTUNII

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INITIAL		NUM		DATE	NAME	CLASS	SUB-CLASS	FILING DATE or § 371(c) Date
	AA2	5,648	,211	07/15/1997	Fraiser et al.			04/18/1984
	AB2	5,654	,142	08/05/1997	Kievits et al.			03/14/1995
	AC2	5,679	,512	10/21/1997	Laney et al.			10/20/1993
	AD2	5,683	,879	11/041997	Laney et al.		-	06/07/1995
	AE2	5,744,308		04/28/1998	Guillou-Bonnici et al.		 	09/26/1995
	AF2	5,766	,849	06/16/1998	McDonough et al.			11/28/1994
	AG2	5,824	,517	10/20/1998	Cleuziat et al.			05/16/1997
	AH2	5,858	,801	01/12/1999	Brizzolara			03/13/1997
	Al2	6,008	,334	12/28/1999	Hanna '			07/23/1997
	AJ2	6,107	,037	08/22/2000	Sousa et al.			06/19/1998
·	AK2	6,107	,039	08/22/2000	Hanna	* .		10/02/1998
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	AS	2	Dunn, J.J. Locations	, and Studier, F. of T7 Genetic El	W., "Complete Nucleotide S lements," J. Mol. Biol. 166:4	equence of Bact 77-535, Academi	eriophage T7 D ic Press, Inc. (1	NA and the 983)
	AT	2	Gait, M.J., Oxford Un	<i>et al.</i> , "Oligoribo iversity Press, C	onucleotide synthesis," in <i>Ol</i> oxford, Great Britain, pp. 25-	igonucleotides ai 31 (1992)	nd Analogues, E	Eckstein, F., ed.,
EXAMINER			L				CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

APPLICATION NO.

To be assigned (National Phase of PCT/g52504/018834)

FIRST NAMED INVENTOR Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004 ART UNIT
To be assigned

				U.S. P	ATENT DOCUMENTS			
EXAMINER INITIAL		NUME		DATE	NAME	CLASS	SUB-CLASS	
	AA3	5,399,	,491	03/21/1995	Kacian et al.			03/19/1992
	AB3	5,888,	,819	03/30/1999	Goelet et al.			03/05/1991
	AC3	5,554,	,516	09/10/1996	Kacian et al.			12/02/1993
	AD3	5,571,	,669	11/05/1996	Lu et al.			01/14/1993
	AE3	6,251,	,594 B1	06/26/2001	Gonzalgo et al.			06/09/1998
	AF3	2003/0	0099950 A1	05/29/2003	Hanna, M.M.			10/30/2001
	AG3	5,503,	,979	04/02/1996	Kramer et al.			08/26/1994
	АН3	6,114,	,519	09/05/2000	Cole et al.			10/15/1997
	Al3	2002/0	0168641	11/14/2002	Mortensen et al.	·		03/09/2001
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	AR	<u>3</u>	practical ap	proach, Gait, M	to Modern Methods of DN .J., ed., Oxford University transcribed from DNA at the	Press, Oxford, Gr	eat Britain, pp.1	-22 (1984)
	AS	3	Guatelli, J.C	rsion," <i>Proc. Na</i>	tl. Acad. Sci. USA 75:645- ermal, in vitro amplification dication," Proc. Natl. Acad.	649, National Aca	ademy Press (19	e reaction
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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	AS	<u>6</u>	Lewis, M.Polymeras Biology (1	se II," <i>J. Biol.</i> C	s, R.R., "Transcriptior hem. 255:4928-4936	n of Simian V , American S	irus 40 DNA ociety for Bio	by Wheat Gern ochemistry and	n RNA Molecular
- FVAAIII-TED	AT	<u>6</u>	Martin, C. ² 27:3966-3	Г., <i>et al.</i> , "Proc 974, American	essivity in Early Stage Chemical Society (19	es of Transcr 988)			se," Biochemistry
EXAMINER							DATE	CONSIDERED	

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To be assigned (National Phase)
PCTA152004/0430214

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004 ART UNIT To be assigned

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AT	7	Montema	gno, C., and Ba	achand, G., "Constructing r	ng, Ltd. (1999)		biomolecular
	AD7 AE7 AF7 AG7 AH7 AJ7 AK7 AN7 AN7 AO7 AP7	AD7 AE7 AF7 AG7 AH7 AJ7 AK7 AK7 AN7 AN7 AO7 AP7 AS 7	AD7 AE7 AF7 AG7 AH7 AI7 AJ7 AK7 DOCUMENT NUMBER AL7 AM7 AN7 AN7 AO7 AP7 OTHER AR Z Meyer, K Deoxyuria American AS Z Milligan, Enzymol.	AB7 AF7 AG7 AH7 AI7 AJ7 AK7 BOCUMENT DATE AL7 AM7 AN7 AN7 AN7 AO7 AP7 OTHER (Including A Deoxyuridine Phosphora American Chemical Social Soc	AB7	AB7 AF7 AG7 AH7 AI7 AI7 AI7 AI7 AK7 FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER DATE COUNTRY CLASS AL7 AM7 AN7 AN7 AN7 AO7 AP7 OTHER (Including Author, Title, Date, Pertinent Pages, etc.) AR Z Meyer, K.L., and Hanna, M.M., "Synthesis and Characterization of a Ne Deoxyuridine Phosphoramidite for Site-Specific Modification of DNA," E American Chemical Society (1996) AS Z Milligan, J.F., and Uhlenbeck, O.C., "Synthesis of Small RNAs Using T. Enzymol. 180:51-62, Academic Press, Inc. (1989) AT Z Montemagno, C., and Bachand, G., "Constructing nanomechanical dev motors," Nanotechnology 10:225-231, IOP Publishing, Ltd. (1999)	AB7 AB7 AF7 AF7 AF7 AH7 AI7 AI7 AI7 AK7 FOREIGN PATENT DOCUMENTS DOCUMENT DATE COUNTRY CLASS SUB-CLASS AL7 AM7 AM7 AN7 AN7 AO7 AP7 OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Meyer, K.L., and Hanna, M.M., "Synthesis and Characterization of a New 5-Thiol-Protein Deoxyuridine Phosphoramidite for Site-Specific Modification of DNA," Bioconjugate Che American Chemical Society (1996) AS Z Milligan, J.F., and Uhlenbeck, O.C., "Synthesis of Small RNAs Using T7 RNA Polymera Enzymol. 180:51-62, Academic Press, Inc. (1989)

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FORM PTO-1449

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ATTY. DOCKET NO. 2072.0010009/MAC/SJE

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To be issigned with a massing PC to 152 604/6-3031

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004 ART UNIT To be assigned

U.S. PATENT DOCUMENTS EXAMINER DOCUMENT INITIAL NUMBER DATE **CLASS** SUB-CLASS **FILING DATE** NAME AA8 AB8 AC8 AD8 AE8 AF8 AG8 AH8 AI8 AJ8 AK8 FOREIGN PATENT DOCUMENTS (%) **EXAMINER** DOCUMENT INITIAL NUMBER COUNTRY **CLASS** SUB-CLASS TRANSLATION DATE Yes AL8 No Yes 8MA No Yes AN8 No Yes **80A** No Yes AP8 No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Mullis, K., et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," AR 8 Cold Spring Harb. Symp. Quant. Biol. 51:263-273, Cold Spring Harbor Laboratory (1986) Mullis, K.B., et al., "The Polymerase Chain Reaction: Why It Works," in Polymerase Chain Reaction, AS 8 Erlich, H.A., et al., eds., Cold Spring Harbor Laboratory Press, Woodbury, N.Y., pp. 237-243 (1989) Nelson, P.S., et al., "Bifunctional oligonucleotide probes synthesized using a novel CPG support are able to detect single base pair mutations," Nucleic Acids Res. 17:7187-7194, Oxford University Press ΑT <u>8</u> (1989)**EXAMINER** DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

Page 9 of 21

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INT'L APPL. FILING DATE: April 29, 2004 ART UNIT To be assigned

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	АТ	Sinha, N.D., and Striepeke, S., "Oligonucleotides with reporter groups attached to the 5'-terminus," in Oligonucleotides and Analogues: A Practical Approach, Eckstein, F., ed., Oxford University Press pp. 185-189, 200-201 (1992)							

To be assigned

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

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ATTY. DOCKET NO.	APPLICATION NO.
2072.0010009/MAC/SJE	To be assigned (National Phase of
	PC /US2904/67388 775
FIRST NAMED INVENTOR	400032113
Michelle M. Hanna	
INT'L APPL. FILING DATE:	ART UNIT

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April 29, 2004

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

Page 11 of 21 APPLICATION NO.

FIRST NAMED INVENTOR

Michelle M. Hanna
INT'L APPL. FILING DATE: April 29, 2004

ART UNIT To be assigned

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE APPLICATION NO.

To be assigned (National Phase of PCI/III32404(81803))

FIRST NAMED INVENTOR Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004

ART UNIT
To be assigned

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	AS	12 Ar	ntequerra cad. Sci.	, F., and Bird, <i>USA 90</i> :11995	A., "Number of CpG isla i-11999, National Acade	ands and genes in hun emy of Sciences (1993	nan and mouse,)	" Proc. Natl.
	АТ	12 Ca	allahan, f	R., <i>et al.</i> , "Freq of Sciences (19	uent Mutations in Breas	t Cancer," Ann. N.Y. A	Acad. Sci. 698:2	1-30, New York
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

APRICATIONNO.

To be assigned National Phase of PCT/US2004/013031)

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004

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	AS	<u>13</u>	Ovarian Ti	I., et al., "Promumors," <i>J. Natl.</i> Nexis Academ	oter Hypermethylation Cancer Inst. 92:564-5 ic database)	and BRCA1 Inactivat 59, Oxford University	ion in Sporadic Br Press (April 2000	east and)). (Retrieved
	АТ	<u>13</u>	Frommer, residues ir Sciences (n individual DN	enomic sequencing pro A strands," <i>Proc. Natl.</i> .	tocol that yields a po Acad. Sci. USA 89:18	sitive display of 5- 327-1831, Nationa	methylcytosine Il Academy of
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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE APPLICATION NO.
To be assigned National Phase 5
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FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004

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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

APPLICATION NO
To by as lighted in Mijorial Phase at PCTHUS 2004/013861

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004

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	AS	<u>15</u>	Horii, A., et al., "Frequent Replication Errors at Microsatellite Loci in Tumors of Patients with Multiple Primary Cancers," Cancer Res. 54:3373-3375, American Association for Cancer Research (1994)							
	АТ	<u>15</u>	Issa, JP.J., human colon	et al., "Methylat ," Nat. Genet. 7	ion of the oestrogen red :536-540, Nature Publis	ceptor CpG island lin shing Co. (1994)	ks ageing and	neoplasia in		
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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

APPLICATION NO.

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FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004 ART UNIT
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	AS	<u>16</u>	Langer, P.R., et al., "Enzymatic synthesis of biotin-labeled polynucleotides: Novel nucleic acid affinity probes," <i>Proc. Natl. Acad. Sci. USA 78</i> :6633-6637, National Academy of Sciences (1981)								
	АТ	<u>16</u>			oe May Be Required for Multis ociation for Cancer Research		genesis," <i>Can</i> o	cer Res.			
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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ATTY. DOCKET NO. 2072.0010009/MAC/SJE

FIRST NAMED INVENTOR

Michelle M. Hanna

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	AS	<u>17</u>			Evolution of Tumor Cell Incement of Science (1976		e <i>194</i> :23-28, An	nerican
	AT	<u>17</u>	Palmisand Sputum,"	o, W.A., et al., "(Cancer Res. 60	Predicting Lung Cancer b :5954-5958, American As	y Detecting Aberrant	Promoter Meth Research (Nov	ylation in vember 2000)
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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE

APPLICATION NO.
To be assigned (Mational Phase of Put Us 2004) (Span)

FIRST NAMED INVENTOR Michelle M. Hanna

INT'L APPL. FILING DATE:

April 29, 2004

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	AS	<u>18</u>	Rice, J.C., et al., "Aberrant methylation of the BRCA1 CpG island promoter is associated decreased BRCA1 mRNA in sporadic breast cancer cells," Oncogene 17:1807-1812, Stor (1998)							
	АТ	<u>18</u>		, K.D., "DNA m Group (May 20	ethylation, methyltransfer 001)	rases, and cancer," (Oncogene 20:31	39-3155, Nature		
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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.0010009/MAC/SJE APPLICATION NO.

To be as in the literal process of PC 1/10/2004 (A) (A)

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004 ART UNIT
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	AS	<u>19</u>	Toyota, M., Biol. 9:349-3	and Issa, JF 357, Academi	P.J., "CpG island methylat c Press (1999)	or phenotypes in agi	ng and cancer,"	Semin. Cancer
	АТ	<u>19</u>			P.J., "The role of DNA hyp /erlag GmbH (January 20		nan neoplasia,"	Electrophoresis
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

and not considered. Include copy of this form with next communication to Applicant.

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APPLICATION NO.

To be assigned (National Phase of PCT/J/S2)04/01e08/11

FIRST NAMED INVENTOR

Michelle M. Hanna

INT'L APPL. FILING DATE: April 29, 2004

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2072.00.10009/MAC/SJE APPLICATION NO.

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FIRST NAMED INVENTOR

Michelle M. Hanna

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